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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/075,914	02/14/2002	Chandru Chandrasekaran	01-462	1739

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EXAMINER	
WEBB, SARAH K	

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 05/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	10/075,914	CHANDRASEKARAN, CHANDRU	
	Examiner	Art Unit	
	Sarah K Webb	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *2/14/02* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *09/10/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. Figures 1,2,4, 5a, 5b, and 9b should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance. Figure 1 is Figure 1 in US 6,245,103, and Figure 2 is half of Figure 2 in the same patent. Figure 4 is Figure 1 in US 5,766,710. Figures 5a and 5b are Figures 1a and 1b in US 5,626,611. Figure 9b is Figure 2 in US 5,282,860. Examiner is uncertain whether the remainder of the Figures are included in prior art.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 7, 11,12,14, 16,17, 19, 23, 24, and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 7 is indefinite, because it is unclear whether the stent should be balloon expandable or self-expandable. Claim 11 states limitations of metallic filaments, but the preceding claim (10) does not require the stent to have filaments. Claim 12 states limitations of a patterned tubular metallic sheet, but the preceding claim (10) does not require for the stent to have this structure. The term "and/or" in claims 14, 16, and 23 is indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-10, 13,15,18,2-22, 25, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,824,049 to Ragheb et al.

Ragheb discloses a stent that can be adapted for endovascular, coronary, biliary, urinary, and tracheal purposes (abstract, line 3). The stent includes a metallic component in the form of an interconnected network of segments, as shown in Figure 7. Ragheb explains that the structure can be in the form of helix (column 6, line 46). The material of the metallic component (14) can be nitinol (column 7, line 35), as well as stainless steel and tantalum. Regarding claim 27, Ragheb explains that the surface of the metallic component (14) can be passivated (column 14, lines 50-55).

The stent base (14) is laminated between multiple layers of biodegradable polymers, as shown in Figures 1-5. Some biodegradable polymers that can be used for layers are polylactic acid, polycaprolactone, and polyglycolic acid (column 11, line 65 through column 12, line 1). The different layers can be formed from different polymers, as this gives the layers different degradation rates (column 13, lines 23-24).

4. Claims 1, 5-10, 12,13, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,725,567 to Wolff et al.

Wolff discloses a stent (10) that includes a metallic component and a biodegradable polymeric material covering the metallic component. The metallic component (22) of the stent can be either braided (Figure 1) or formed as interconnected segments (Figure 2). Both structures have a plurality of apertures. Figures 4 and 14 more clearly illustrate the polymeric coating layers (14) disposed over the metallic filaments (22 or 16, respectively). The embodiment of the braided strands in Figure 14 shows that the polymeric material (18) provides support for the filaments (12), in that "the bonding at the juncture prevents the individual filaments from sliding relative to each other, which improves radial strength" (column 7, lines 20-22). Wolff explains that the polymer layer (14) is biodegradable and carries drugs (column 6, lines 45-46). The polymer material can be polylactic acid/polyglycolic acid (column 7, line 46), which meets the limitations of claim 5. The drugs contained in the polymer layer can be antiplatelet or anticoagulant (column 5), which are therapeutic.

Wolff explains that the stent can be endovascular, biliary, tracheal, etc. (column 1, lines 55-62). The stent can be either self-expandable or balloon expandable (column 9, line 66 through column 10, line 2).

The limitations of claim 12 only pertain to the process by which the patterned sheet is formed, so this is considered to be a product by process claim. Whether a product is patentable depends on whether it is known in the art or it is obvious, and is

not governed by whether the process by which it is made is patentable. Therefore, the limitations of claim 12 were not given patentable weight.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 2 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolff in view of US Patent No. 5,630,840 (Mayer).

Wolff includes all the limitations of claim 11, except for the filaments comprising more than one metal. Mayer discloses a self-expanding braided stent (16) in Figure 1 that is similar to the structure of the Wolff braided stent. Mayer explains that in Figure 4 the core (24) is made of a radiopaque material, and the case (26) is made of a highly resilient material (column 6, lines 1-16). As shown in Figures 13 and 14, the filaments (80,88) can have three layers of different metals. Mayer teaches that it is desirable for stents to be both mechanical stable and highly radiopaque for imaging (column 2, lines 24-30). Mayer also teaches that titanium, tantalum, and cobalt alloys and stainless steel are suitable for the stent material (column 3, line 61- column 4, line 14). It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the filaments of the Wolff stent from two different metals, as Mayer teaches that

such a combination can provide a stent that is both mechanically stable and visible under fluoroscopy or x-rays.

6. Claims 14,16, 17,19, 23,24, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ragheb in view of Wolff.

Ragheb includes layers of therapeutic agents, which are listed from column 8 to column 10. Ragheb states that separate layers can include different therapeutic agents, and this allows the stent to perform more functions (column 13, lines 8-16). Ragheb also states that layers of different polymers can give bioactive agents different release rates (column 13, lines 23-24). Ragheb explains that a single layer can include two different therapeutic agents, because it is sometimes desirable to deliver two agents to tissue at the same time (column 16, lines 15-25).

Ragheb includes all the limitations of claims 14,16,17,19, 23, 24, and 26, but includes the therapeutic agent as a separate layer from the polymer layer. Wolff and Ragheb form the polymer layer from similar materials (PLA and PGA), and they are both intended for controlled release of therapeutic agents. Wolff teaches these polymers can carry therapeutic agents for controlled release of the drug (column 7, lines 40-45). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the therapeutic agent and polymer layers of Ragheb into one layer, as taught by Wolff, as this is simply an alternate way to accomplish controlled release of a drug by a polymer layer of a stent.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6,652,575 (Wang) and US 6,174,329 (Callol) include elements of the claimed stent.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah K Webb whose telephone number is (703) 605-1176. The examiner can normally be reached on Mon-Fri 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on (703) 308-2496. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SKW
04/28/04

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